The mandate of the Canadian Coordinating Office for Health Technology Assessment (CCOHTA) has always included the identification and assessment of new and emerging health technologies that may have a significant impact on health care in Canada. Several CCOHTA publication series were developed to cover information in this area, but there was still a gap in the provision of information on new and emerging non-drug technologies, for which information is typically scarce. 

Health Technology Update aims to fill this gap and bring you the latest information on innovative medical devices, diagnostics and procedures that are topical in Canada.

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Our goals are to reduce duplication of effort in the early assessment of health technologies; and to highlight links to organizations that have had some experience with the technology or that may be grappling with the same issues.

This inaugural issue of Health Technology Update includes articles about a minimally invasive procedure to treat obstructive sleep apnea and snoring; ovarian tissue autotransplantation; an implantable device for the treatment of obesity; and some of the complex issues surrounding the funding and use of positron emission tomography (PET) scanners in Canada. Also included is an introduction to the new CCOHTA Health Technology Inquiry Service, and a list of recent publications that might be of interest to those involved in health care in Canada.

We hope that you will find this issue of the Health Technology Update informative and useful.

The Point Prim Lighthouse, PEI.

Photo courtesy of Tourism PEI/John Sylvester

We welcome your feedback on the newsletter. Please send comments to:

Catherine Allison, Editor
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A minimally invasive surgical treatment for obstructive sleep apnea is gaining the attention of ear, nose and throat specialists in the US.

Palatal implants are tiny, braided, polyester threads placed in the soft palate (at the back of the roof of the mouth) to reinforce and stiffen tissues that often flutter and obstruct the upper airway.

Obstructive sleep apnea and excessive snoring are the result of airway blockage when tissues at the back of the throat collapse and close during sleep, causing pauses in breathing or shallow breathing and poor sleep.

An estimated 4% of Canadian men and 2% of Canadian women have obstructive sleep apnea, with chronic daytime sleepiness.1

Sleep apnea is also associated with an increased risk of more severe health problems, such as high blood pressure, stroke, and heart attack.3

During the palatal implant procedure, three segments of thread are permanently embedded in the palate during an office visit. This is done under local anesthesia, using a small disposable delivery tool. The threads, which are 18.0 mm long and 1.5 mm in diameter, cannot be seen once they are in place. There is little pain associated with the procedure and most patients resume normal activities and diet the same day.3

Regulatory status

The Pillar™ Palatal Implant System received US Food and Drug Administration (FDA) approval in February 2004, for the treatment of patients with mild to moderate obstructive sleep apnea.5

John Foster, senior vice-president of commercial operations at implant manufacturer Restore Medical Inc., said that his company will decide in the next six to nine months when an approval application will go to Health Canada.

Cost

Mr. Foster reported that the procedure costs up to US$2,500, including US$750 for the set of three implants.

Evidence of effectiveness

In a small, non-randomized European clinical trial funded by Restore Medical, 46 non-obese adults with mild to moderate obstructive sleep apnea (defined as 10 to 30 episodes of upper airway obstruction per hour) received the palatal implants. Ninety days after the procedure, the number of apnea episodes was halved in more than ¾ of patients. After treatment, 23 patients (50%) no longer met the criteria for mild to moderate obstructive sleep apnea, as the number of apnea episodes decreased to less than 10 per hour. Five patients did not have a significant decrease in apnea. Two patients had the implant removed after partial extrusion occurred. No serious adverse events were reported.5 Further clinical trial results are expected to be published in 2005. No studies have compared the palatal implants with continuous positive airway pressure (CPAP), or to other treatments for sleep apnea.

References


A 28-year-old Israeli woman, who was cured of non-Hodgkin’s lymphoma, gave birth to a healthy baby in June 2005 after her own banked ovarian tissue was re-implanted.1

The woman’s tissue was removed and preserved in a freezer before she received high-dose chemotherapy, a treatment that is known to cause ovarian failure. Two years after her complete recovery, the tissue was re-implanted, and this resulted in the production and retrieval of a mature egg. After the egg was fertilized in vitro with her husband’s sperm, the resulting embryo was transferred to her uterus, where the fetus developed normally.

This appears to be the third reported case of a woman giving birth after receiving transplanted ovarian tissue.

In June 2005, an infertile woman received an ovarian tissue transplant from her identical twin sister and gave birth to a baby after normal conception.2

Last year, a team of Belgian physicians announced that a 32-year-old woman who was cured of Hodgkin’s disease had given birth to a baby after her ovarian tissue, which was frozen for six years, was successfully re-implanted.3

Cryopreservation of ovarian tissue is one of several options for women who may become infertile after aggressive cancer treatments.

Ovarian tissue is removed by laparoscopy, a surgical procedure in which a scope is inserted through a small incision in the abdomen. The tissue is then preserved in liquid nitrogen and frozen. When the tissue is carefully thawed and re-implanted, fertility drugs may be used to induce ovulation.

Canadian access to the technology

While the procedure is still in its infancy, the McGill Reproductive Centre in Montreal began offering ovarian tissue cryopreservation four years ago.

Dr. Togus Tulandi, a professor of obstetrics and gynecology, and a fertility expert at the McGill centre, said that he has collected ovarian tissue samples from 20 to 30 women. Some women have travelled to the Montreal clinic from Ontario and Nova Scotia.

“So far, we have not transferred any tissue back to the patients,” Dr. Tulandi said. Women must first undergo cancer treatment, then wait for a full remission and recovery before making the decision to conceive a child. None of the McGill centre’s patients have reached this stage yet.

Ovarian tissue banking is not yet offered at any other Canadian sites.

Risks of tissue re-implantation

Candidates for ovarian tissue autotransplantation must be selected carefully because there is a risk that some malignancies, such as lymphoma or leukemia, might be re-introduced through the grafted tissue. More reliable and sensitive screening technologies are needed to detect residual cancer cells.

Other fertility options

Other ways of preserving fertility include ovarian suspension to move the ovaries out of the range of the intended pelvic radiation; cryopreservation of immature and mature oocytes for future in vitro fertilization; or embryo preservation.

References

The Transcend Implantable Gastric Stimulator (IGS®) is a new health device that may help fight “globesity” — a World Health Organization term describing the escalating global epidemic of obesity.

The battery-operated device, made by Medtronic, is implanted under the skin of the abdomen and then attached to two insulated wires that are sutured to the stomach wall. The IGS sends painless electric pulses to the stomach, inducing an early and lasting sensation of “fullness,” possibly by regulating the gut hormones responsible for appetite. The IGS is used in combination with diet and lifestyle modifications.

The surgery
A bariatric surgeon (a physician who specializes in the treatment of obesity) makes a laparoscopic incision to implant the device, and the patient returns home the same day. The surgeon later activates and sets the electrical pulses with a computer and radio-electric wand.

Compared with other surgical options, such as gastric banding and gastric bypass, the IGS is less invasive and does not alter the anatomy or physiology of the gastrointestinal tract.

The evidence
More than 500 patients in randomized, placebo-controlled clinical trials lost an average of 32% of their excess weight after using the device for two years. No serious complications were reported.

Regulatory status
The IGS was approved by Health Canada in December, 2004. The IGS has been sold in Europe for more than three years, but is approved only for investigational use in the United States.

Who might benefit?
According to Health Canada, the IGS is indicated for weight reduction in obese adults with a BMI more than 35. Based on 2004 Statistics Canada data, approximately 1.9 million adult Canadians have a BMI equal to or greater than 35, which is associated with a high risk of high blood pressure, diabetes, and heart disease.

Cost
According to Dustin Ide, senior vice-president of Canadian distributor Xycorp Medical Inc., the device costs C$11,500 and the surgical procedure may cost up to C$12,500. As the IGS is not covered by insurance (public or private), the patient is responsible for all associated costs.

Other developments
Other US companies are developing similar obesity implants that deliver an electrical charge to the stomach.

References

The diagnosis of obesity is based on body mass index (BMI), which is a measure of a person’s weight in relation to their height. An individual with a BMI of 30 or more is considered obese. Source: Statistics Canada

The 60X40X10.3 mm device has insulated wires that run to the stomach wall.
PET scanner update

The positron emission tomography (PET) scanner is a nuclear medicine imaging technology that allows detailed diagnostic measurement of physiological and biochemical bodily processes. This technology can be used to detect and evaluate different types of cancer; or to examine brain function, blood flow or heart disease.

How it works

During a PET scan, a tiny dose of positron-emitting radiopharmaceutical (PER) is administered intravenously before the patient reclines inside a large, doughnut-shaped machine.

When the radioactive tracer travels through the body, radioactive particles decay and release positrons, which pair up with electrons and subsequently emit photons.

Positron-emitting radiopharmaceutical (PER) tracers

One of the most widely used tracers is $^{18}$F-FDG, a radioactive glucose analogue. After injection into a patient’s blood stream, FDG is taken up by the cancer cells at a more rapid rate than normal cells. This allows cancers to be seen as “hot spots” on the PET scan.

PER tracers are produced in a laboratory from radioisotopes generated by a particle accelerator (cyclotron). As most PERs have a short shelf life, ranging from minutes to a few hours, radioisotopes must be produced close to the centres with PET scanners. This may limit patients’ access in some parts of Canada.

PER regulations

PER tracers have not yet been approved for use in Canada. Health Canada requires each site preparing PER tracers to obtain a Clinical Trial Application. In addition, recorded data must be submitted for all patients receiving the tracers.

Location of PET Scanners

Table 1 outlines PET scanner distribution in the five provinces that have adopted the technology, including installations planned for 2005.

Evidence of clinical effectiveness

A large number of primary research studies and systematic reviews have examined the potential benefit of PET scans to manage various cancers.

A rapid review in 2004 by the UK National Health Service, Health Technology Programme, found that there was evidence to support the use of PET scans in the staging of non-small cell lung cancer; the evaluation of recurrent colorectal cancer; and the restaging of Hodgkin’s lymphoma after induction therapy. There was also sufficient evidence to support the use of PET scans to diagnose solitary pulmonary nodules and occult tumours in the head.

Table 1: Location of publicly funded PET scanners and cyclotrons in Canada*

<table>
<thead>
<tr>
<th>Province</th>
<th>Cyclotrons</th>
<th>PET scanners currently in operation†</th>
<th>Additional scanners expected to be operational in 2005</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quebec</td>
<td>2</td>
<td>5</td>
<td>1</td>
</tr>
<tr>
<td>Ontario</td>
<td>3</td>
<td>8</td>
<td>–</td>
</tr>
<tr>
<td>Manitoba</td>
<td>–</td>
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<td>1</td>
</tr>
<tr>
<td>Alberta</td>
<td>1</td>
<td>3</td>
<td>2</td>
</tr>
<tr>
<td>British Columbia</td>
<td>1</td>
<td>3</td>
<td>1</td>
</tr>
</tbody>
</table>

* Data supplied by Henri Vienneau, executive director of the Nuclear Medicine Alliance.
† Includes PET scanners used for patient care (through clinical trials) and scanners used for research purposes only.

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and intractable seizures. A 2003 Norwegian review (English summary published by the International Network of Agencies of Health Technology Assessment (INAHTA)) reported similar conclusions.

Use in other countries

The clinical use of PET scans is routine in the US, many European countries and Japan. In the US, Medicare pays for PET scans for the diagnosis of most cancers, providing that data are submitted to a national PET data registry.

Are PET scans cost-effective?

PET scans may save money in the short term through the elimination of other diagnostic and treatment procedures, such as unnecessary surgery. There are, however, insufficient short-term cost-benefit analyses to draw conclusions and there are no long-term patient outcome studies.

AETMIS, the Quebec health technology assessment agency, developed an economic model to assess the cost-effectiveness of PET scans in non-small cell lung cancer. The cost was deemed to be acceptable for the corresponding life-year gained, but the AETMIS report concluded that the main advantages of PET scans were the improvement in quality of life; the reduction in useless debilitating interventions; and faster access to effective therapy.

ICES, an Ontario-based health research agency, performed a systematic review on the cost-effectiveness of PET in 2001, with subsequent updates to 2004. There were a few non-Canadian studies available for the ICES review, most of low quality. The report concluded that PET is likely to be cost-effective for patients with some cancers and intractable seizures.

**Provincial funding for PET scan operation**

**QUEBEC** provides funding for 1,500 scans annually at each of its four hospitals with PET scanners. Quebec is the only province with a billing code for physician interpretation of the scan. **Source:** Henri Vienneau, executive director of the Nuclear Medicine Alliance, Montreal.

**ONTARIO** is providing funding for approximately 1,500 PET scans per year (over a two-year period) for patients enrolled in five clinical trials and a registry at four geographical sites. Indications covered are non-small cell lung, head and neck, breast and colorectal cancers, as well as single pulmonary nodule and suspected recurrent germ cell, thyroid and colorectal cancer. **Source:** Shirley Lee, Ontario Ministry of Health and Long-Term Care, Medical Advisory Secretariat, Toronto.

**NOVA SCOTIA** plans to buy a PET scanner in 2005 and have a program operating by 2007. Specific operational funding has not been announced. While PERs may be shipped in initially, a cyclotron will be built to support the program. **Source:** Valerie Bellefontaine, Nova Scotia Department of Health, Halifax.

**MANITOBA** is funding up to 1,000 PET scans in the 2005 to 2006 fiscal year for the new PET/CT scanner at the Winnipeg Health Sciences Centre (first patient imaged July 7, 2005). Funding may increase to scan up to 2,000 patients a year thereafter, relative to clinical demand. It is planned that radioactive tracers will be manufactured in Edmonton and air-freighted to Winnipeg. **Source:** Dr. Sandor Demeter, department of radiology, Health Sciences Centre, Winnipeg.

**NEW BRUNSWICK** will provide $1.3 million to cover operational costs for two PET/CT scanners, expected to be operational by September 2006. PERs will be shipped in daily. **Source:** Johanne Le Blanc, Health and Wellness, Fredericton.

**ALBERTA** funds clinical PET scans at the Cross Cancer Institute in Edmonton, from the global regional health budget. **Source:** Dr. Sandy McEwan, Cross Cancer Institute, Edmonton.

**BRITISH COLUMBIA** will fund 1,500 PET scans at the BC Cancer Agency’s Vancouver clinic during the 2005 to 2006 fiscal year. The new PET/CT scanner began operating in June 2005. **Source:** Dr. Don Wilson, BC Cancer Agency, Vancouver.

**References**


New and emerging health technology reports
Recent publications from CCOHTA and other HTA agencies

Australia and New Zealand Horizon Scanning Network

Combined CT and PET scanner for carcinosomas

Blue Cross Blue Shield Technology Evaluation Centre

Gene expression profiling for managing breast cancer treatment
Genetic markers may identify women with node-negative breast cancer who would benefit from adjuvant chemotherapy – potentially allowing many women to avoid unnecessary chemotherapy treatments. However, the available evidence does not yet show the benefit of these tests in patient management or in improving health outcomes. Available: http://www.bcbs.com/tec/vol20/20_03.html

Canadian Coordinating Office for Health Technology Assessment (CCOHTA)

Minimally invasive hip resurfacing
Metal-on-metal hip resurfacing is an emerging alternative to total hip replacement for younger, more active patients with degenerative hip disease. This bulletin explores the potential advantages and disadvantages of using minimal incisions and new techniques in this surgical procedure. Available: https://www.ccohta.ca/publications/pdf/353_mi_hip_resurfacing_cetap_e.pdf

Ontario Medical Advisory Secretariat

Balloon kyphoplasty
Balloon kyphoplasty is a new treatment for vertebral compression fractures commonly caused by osteoporosis. The procedure appears to offer significant clinical advantages compared with alternative treatments. Available: http://www.health.gov.on.ca/english/providers/program/mas/reviews/review_kypho_1204.html

Agence d’évaluation des technologies et des modes d’intervention en santé (AETMIS)

Comparison of the insulin pump and multiple daily insulin injections in intensive therapy for type 1 diabetes

Alberta Heritage Foundation for Medical Research (AHFMR)

Cost estimation of point of care B-type natriuretic peptide for the diagnosis of heart failure in the emergency department: application to Alberta

Portable home hemodialysis
The number of Canadians with kidney failure is increasing, as are the costs associated with treating patients with this condition. Home hemodialysis offers a potentially cost-effective alternative to hospital-based dialysis, and one that may improve both clinical outcomes and quality of life for many patients. Available: https://www.ccohta.ca/publications/pdf/152_No25_Home_dialysis_etech_e.pdf

MRI-guided focused ultrasound for treatment of uterine fibroids
Uterine fibroids are a common health condition in pre-menopausal women and several new treatments have recently become available. Evidence on the effectiveness of using high-intensity focused ultrasound to reduce uterine fibroids is summarized in this bulletin. Available: https://www.ccohta.ca/publications/pdf/361_mri_cetap_e.pdf

CCOHTA is one of many agencies involved in the assessment of new and emerging health technologies, which can also include “older” technologies that have not yet been used extensively. As part of our “horizon scanning,” we check the web sites of other HTA agencies for recent assessments that may be of interest to Canadian health care decision makers. Unless otherwise stated, these publications are available without cost at the web sites shown.
In February 2005, CCOHTA launched a Health Technology Inquiry Service (HTIS). The service gives Canadian decision makers access to health technology assessment information, based on the best evidence that can be located in the time available. The HTIS does not replace full assessments of medical technologies, but is intended to provide information when decision makers require a more immediate response. Information based on the best available evidence is provided in 24 hours to 30 business days, depending on the needs and urgency of the request. Accordingly, the HTIS products range from a list of the best evidence-based information to a formal report that includes an appraisal of the findings.

So far, the HTIS service has responded to more than 100 questions ranging from inquiries about particular medical technologies, such as video capsule endoscopy or home sleep apnea monitoring, to broader questions on the value of screening initiatives or home care for chronic diseases.

Questions for CCOHTA’s inquiry service may be submitted to HTIS staff:

E-mail: HTIS@ccohta.ca
Phone: 1-866-898-8439 (toll free)